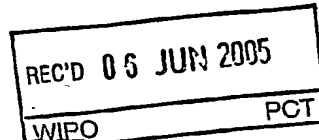


PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY



PCT

To:

Blake Dawson Waldron
Level 39
101 Collins Street
MELBOURNE VIC 3000

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 30 MAY 2005	
FOR FURTHER ACTION See paragraph 2 below	
Applicant's or agent's file reference WJP DAAS0313815085	
International application No. PCT/AU2005/000453	International filing date (day/month/year) 31 March 2005
	Priority date (day/month/year) 31 March 2004
International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ C07D 311/92; A61K 31/352; A61P 31/20	
Applicant MONASH UNIVERSITY et al	

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer R.L. POOLEY Telephone No. (02) 6283 2242
---	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2005/000453

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2005/000453

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-6, 9-11	YES
	Claims 7, 8, 12	NO
Inventive step (IS)	Claims 1-6, 9-11	YES
	Claims 7, 8, 12	NO
Industrial applicability (IA)	Claims 1-12	YES
	Claims	NO

2. Citations and explanations:

The following documents were cited in the International Search Report:

D1 - WO 1995/029920 A

D2 - Chemical Abstracts Online Accession No. 87:167020

D3 - Chemical Abstracts Online Accession No. 83:163943

NOVELTY (N) and INVENTIVE STEP (IS) Claims 7, 8, 12

Document D1 discloses suksdorfin compounds at page 12 that overlap with the compounds of present claims 7 and 8 when present substituent R₄ is OH or OR₉. Document D1 also discloses pharmaceutical compositions that include these compounds. Accordingly claims 7, 8 and 12 lack novelty and inventive step in light of document D1. Note however that the overlap between the present compounds and those of document D1 would be removed if the reference to R in the proviso of claim 7 was changed to R₄, as at page 3 line 10 of the present specification.

Documents D2 and D3 disclose compounds wherein a methyl group is present at the location of present substituent X. As the definition of X does not include a methyl group claims 1-12 are novel and inventive over the disclosures of documents D2 and D3.

The above documents do not disclose the methods of claims 1-6, and the compounds of claims 9-11. Accordingly these claims are novel and inventive over the disclosures of documents D1, D2 and D3.

INDUSTRIAL APPLICABILITY (IA)

Claims 1-12 meet the requirements of industrial applicability.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2005/000453

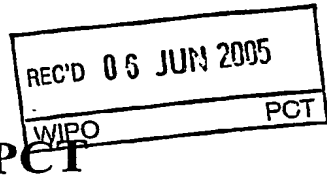
Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 7 is unclear because it does not include a definition of the substituents R_6 and R_7 which are present in Formula 1 at the top of page 56. Additionally, the reference to the substituent R in the proviso at page 56 line 18 appears to be incorrect and is inconsistent with the description at page 3 line 10 where R_4 is OH.

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY



To:

Blake Dawson Waldron
Level 39
101 Collins Street
MELBOURNE VIC 3000

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 30 MAY 2005	
FOR FURTHER ACTION See paragraph 2 below	
Applicant's or agent's file reference WJP DAAS0313815085	
International application No. PCT/AU2005/000453	International filing date (day/month/year) 31 March 2005
	Priority date (day/month/year) 31 March 2004
International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ C07D 311/92; A61K 31/352; A61P 31/20	
Applicant MONASH UNIVERSITY et al	

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer R.L. POOLEY Telephone No. (02) 6283 2242
--	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2005/000453

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2005/000453

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-6, 9-11	YES
	Claims 7, 8, 12	NO
Inventive step (IS)	Claims 1-6, 9-11	YES
	Claims 7, 8, 12	NO
Industrial applicability (IA)	Claims 1-12	YES
	Claims	NO

2. Citations and explanations:

The following documents were cited in the International Search Report:

D1 - WO 1995/029920 A

D2 - Chemical Abstracts Online Accession No. 87:167020

D3 - Chemical Abstracts Online Accession No. 83:163943

NOVELTY (N) and INVENTIVE STEP (IS) Claims 7, 8, 12

Document D1 discloses suksdorfin compounds at page 12 that overlap with the compounds of present claims 7 and 8 when present substituent R₄ is OH or OR₉. Document D1 also discloses pharmaceutical compositions that include these compounds. Accordingly claims 7, 8 and 12 lack novelty and inventive step in light of document D1. Note however that the overlap between the present compounds and those of document D1 would be removed if the reference to R in the proviso of claim 7 was changed to R₄, as at page 3 line 10 of the present specification.

Documents D2 and D3 disclose compounds wherein a methyl group is present at the location of present substituent X. As the definition of X does not include a methyl group claims 1-12 are novel and inventive over the disclosures of documents D2 and D3.

The above documents do not disclose the methods of claims 1-6, and the compounds of claims 9-11. Accordingly these claims are novel and inventive over the disclosures of documents D1, D2 and D3.

INDUSTRIAL APPLICABILITY (IA)

Claims 1-12 meet the requirements of industrial applicability.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2005/000453

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 7 is unclear because it does not include a definition of the substituents R_6 and R_7 which are present in Formula 1 at the top of page 56. Additionally, the reference to the substituent R in the proviso at page 56 line 18 appears to be incorrect and is inconsistent with the description at page 3 line 10 where R_4 is OH.